

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference BP/G-33315A/BCK	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/EP2004/009055	International filing date (day/month/year) 12/08/2004	(Earliest) Priority Date (day/month/year) 13/08/2003
Applicant SANDOZ AG		

This International Search Report has been prepared by this international Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☒ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☒ none of the figures is to be published with the abstract.

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Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:

a. type of material

☒

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☒

in written format

☒

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed

☐

filed together with the international application in computer readable form

☒

furnished subsequently to this Authority for the purpose of search

2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

3. Additional comments:

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-12 (all completely), 14-19 (all partially)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-12 (all completely),14-19 (all partially)

A process to release a recombinant polypeptide of interest from the periplasm of the host cells by applying an osmotic shock directly on the host cells in the fermentation medium.

2. claims: 13,20-23 (all completely),14-19 (all partially)

A process for the purification of a recombinant interferon alpha 2 from a crude preparation of interferon alpha 2 by applying a specific sequence of several chromatographic steps as defined in claim 13 (i) to (v).

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12P21/00 C07K14/56

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12P C07K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, EMBASE, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	HART R A ET AL: "LARGE SCALE, IN SITU ISOLATION OF PERIPLASMIC IGF-I FROM E. COLI" BIO/TECHNOLOGY, NATURE PUBLISHING CO. NEW YORK, US, vol. 12, November 1994 (1994-11), pages 1113-1117, XP001153305 ISSN: 0733-222X the whole document ----- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

14 April 2005

Date of mailing of the international search report

05-07-2005

Name and mailing address of the ISA

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Schneider, P

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FRENCH C ET AL: "DEVELOPMENT OF A SIMPLE METHOD FOR THE RECOVERY OF RECOMBINANT PROTEINS FROM THE ESCHERICHIA COLI PERIPLASM" ENZYME AND MICROBIAL TECHNOLOGY, STONEHAM, MA, US, vol. 19, no. 5, 1996, pages 332-338, XP000886796 ISSN: 0141-0229 the whole document -----	
A	DALMORA S ET AL: "Analysis of recombinant human growth hormone directly in osmotic shock fluids" JOURNAL OF CHROMATOGRAPHY A, ELSEVIER SCIENCE, NL, vol. 782, no. 2, 10 October 1997 (1997-10-10), pages 199-210, XP004096275 ISSN: 0021-9673 the whole document -----	
A	WO 89/00201 A (THE UNIVERSITY OF DUNDEE) 12 January 1989 (1989-01-12) the whole document -----	
A	WO 03/004599 A (INSIGHT STRATEGY & MARKETING LTD; PELEG, YOAV; PANCER, ZEEV; INSIGHT B) 16 January 2003 (2003-01-16) the whole document -----	

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Information on patent family members

International Application No

PCT/EP2004/009055

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 8900201	A	12-01-1989	WO 8900201 A1	12-01-1989
			GB 2206881 A	18-01-1989

WO 03004599	A	16-01-2003	WO 03004599 A2	16-01-2003
